use in the community (spillover effect). **CONCLUSIONS:** Evergreening drugs successfully compete with generics, offsetting cost containment strategies including generic medication substitution or a hospital RDF, particularly so if hospitals include evergreening or brand drugs on their RDF. For effectiveness, prescriptions should be coordinated at the state level rather than from a payer perspective, or hospitals should implement strategies to systematically switch patients to generic drugs at discharge.

PHP13

THE EFFECT OF LAW FOR ECONOMICAL USE OF MEDICATIONS 2006 ON THE NUMBER OF PHARMACIES BETWEEN 2007-2010

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OBJECTIVES: In 2006 a law for the economical use of medications was introduced into the Hungarian legislation. This law – among others – facilitated the foundation of new pharmacies. The aim of our study is to analyse the effect of that legislation on the number of pharmacies. **METHODS:** Data were derived from the pharmaceutical database of the Hungarian Health Insurance Fund Administration (OEP), the only health care financing agency in Hungary. We analysed the 5 years period between 2006-2010. The number of pharmacies were analysed according to the number of population of different settlements. **RESULTS:** The number of community pharmacies increased from 2030 (2006) to 2576 (2010) by 546 pieces (26.9 %). The number of pharmacies showed a different pattern according to the size of population of settlements. In villages with a population of 0-449, 500-999 and 1000-1999, the number of pharmacies decreased (3 pieces / 3.6 %; 18 pieces / 20.0 %; 23 pieces / 10.6 % respectively). In cities with a population between 2000-4999 we found a slight increase in the number of pharmacies (11 pieces / 3.0 %). In bigger towns there was a clear increase in the number of pharmacies: 5000-9999 population 53 pieces / 29.0 %; 10000-49999 194 pieces / 37.1 %; 50000-99999 population 129 pieces / 33.0 % and over the population of 100000: 158 pieces / 42.9 %. **CONCLUSIONS:** After the introduction of the new law for the economical use of medications in 2006, the number of pharmacies significantly changed in Hungary. However, this change in the number of pharmacies was inequal according to the size of the population: in villages with a population lower than 2000 people there was a decrease, while in cities with bigger population the number of pharmacies significantly increased.

PHP14

2010-2012 GLOBAL HEALTH CARE REFORMS AND THEIR IMPACT ON PRICING, ACCESS AND HEALTH OUTCOMES STRATEGY

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OBJECTIVES: During 2009-2012 major health care reforms were proposed and implemented in a number of nations, for example, Affordable Care Act in the United States, AMNOG in Germany, HSPT in France, KVG in Switzerland, Ustawa Refundacyjna in Poland and NHS proposed reform in the UK. These reforms have major implications on pricing, market access and HEOR strategy for drug and device products. **METHODS:** To understand the implications of these trends, we analyzed 2009-2012 reform bills and proposed changes worldwide. Additionally, we interviewed public and private payers, key opinion leaders and payer-influencers to understand implications of these reforms on drug and device manufacturers. Stakeholders ranked various data collection methods on a scale of 1-10 (1-least important and 10-most important). **RESULTS:** The global health care landscape is expected to undergo significant change during 2012-2016. In the United States, government will play increased role as a single payer, especially with?Medicare, Medicaid and CHIP programs? which will cover 114 million Americans, at a cost of $784 billion. In Germany, AMNOG bill marked the end of free drug pricing and would lead to increased insurance premiums (now 15.5% of wages). In the UK, NHS has proposed to replace PCTs with 500-1000 GP-led consortia and use value-based pricing for expensive drugs and devices. Randomized controlled trial, budget impact model and systematic reviews —ranked highest (7.5-9.1) among payers. Overall, payers view that in the future, health economic assessments would play critical role in pricing, coverage and reimbursement of branded products. **CONCLUSIONS:** This analysis shows that global health care landscape is expected to undergo significant change during 2012-2016. Discussions with payers, KOLs and payer-influencers highlights increased importance of HEOR data in the future.

PHP15

THE IMPACT OF ORPHAN DRUG INCENTIVES ON INNOVATION AND PRICING IN NICHE THERAPEUTIC MARKETS: A SYSTEMATIC REVIEW OF THE LITERATURE

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OBJECTIVES: To review the impact orphan drug (OD) legislation has had on innovation and pricing of therapeutic products for rare diseases in the US, EU, and Japan. **METHODS:** A systematic literature review was conducted, seeking English-language studies published after the enactment of initial OD legislation in 1983. EMBASE, Medline, and Business Source Complete were searched and results screened for studies specifically assessing the impact of industry-focused policy interventions using 1) measurable innovation- and pricing-related outcomes, and 2) specifying appropriate comparators. In addition to being abstracted for information on research setting, counterfactuals, outcomes, and findings, the methodological quality of included studies was evaluated with an adapted tool. **RESULTS:** Twenty unique studies met the inclusion criteria: 14 discussing innovation outcomes and 7 discussing pricing outcomes. Increasingly strong study designs have been used to validate that that OD legislation has increased cross-market approvals and suggest the increasing role of small biotechnology companies. Select research also shows a positive relationship between disease prevalence and the likelihood of indicated ODs and is bolstered by well-controlled regression-continuity studies showing sustained innovation in higher prevalence OD markets. However, some concerns are raised regarding innovation in low prevalence conditions and conditions just above OD thresholds. Pricing studies were almost exclusively focused on the EU. A multiple-regression analysis demonstrated that merely having an OD designation leads to a higher price, with 4 weaker studies suggesting an inverse relationship between rare disease prevalence and acquisition price. **CONCLUSIONS:** Despite an abundance of opinion and case study pieces in OD literature, specific studies of high internal validity exist, as do defined and usable comparator group classifications. The reviewed studies ought to serve as valuable information for policymakers considering policy extensions for ultra-orphans, international markets, or other niche therapeutic areas, as well as demonstration of best-practices in designing well-controlled studies evaluating biopharmaceutical policies.

PHP16

GENERIC DRUG MARKET ACCESS IN JAPAN

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The Japanese generic drug market is not well developed. The generic volume share is 20% of the total market vs. 74% and 64% in the USA and UK. The slow uptake of generics is often explained by the "Brand Lover" profile of Japan. No formal review of drug policy has been undertaken to understand the slow uptake of generics. **OBJECTIVES:** To review the current Japanese drug policy regarding generic drugs and to appreciate the incentive and disincentive to use generic. **METHODS:** We reviewed the current Japanese generic drug policy enacted by the Ministry of Health, Labour and Welfare (MHLW), and the Japanese Generic Medicines Association's website. **RESULTS:** Major policies to enhance generic uptake were issued in 2002, 2006 and 2010. They required that prescriptions specify if substitution generics are acceptable, and provide some modest financial incentives for pharmacies and hospitals to substitute only with the patient's agreement. In 2012, INN prescription is encouraged but not requested. The recent introduction of Japanese DRG hospital funding, and the 2011 Japan-India Economic Partnership Agreement, which opened the Japanese market to Indian generic drug manufacturers, are expected to boost the generic market. However, small pricing gaps between generic and branded drugs, the lack of mandatory substitution and INN prescription, little price discounting and little education towards the public might explain the slow uptake of generics in Japan, relative to the West. **CONCLUSIONS:** Although the "Brand Lover" assumption is candidly used to explain the lack of traction by generic drugs, this review finds the lack of policy incentives to boost generic adoption, better explain current levels of generics penetration. Shall the authorities be willing to encourage generic uptake more effective policy incentive are needed.

PHP17

ROLE OF SUBGROUP ANALYSES FOR TECHNOLOGY ASSESSMENT AND COVERAGE DECISIONS

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OBJECTIVES: Cost effectiveness analyses play a critical role in determining coverage of novel drugs and devices. Increasingly, payers are demanding subgroup analyses to determine indications which would be covered by the national health system or insurance agency. **METHODS:** To understand and review trends in use of subgroup cost effectiveness analysis, we analyzed NICE HTAs for products approved in 2011-2012. Manufacturer submissions for CEA were compared to final review and decision by HTA agency. Analogs were identified and case studies were developed to further understand the use of subgroup analyses and cost effectiveness models. **RESULTS:** Decisions made by NICE in 2011-2012 show increasing trends towards the use of subgroup analysis for determining indications for coverage by national payer bodies. During 2011-2012, 80% of the assessments included subgroup analyses. Approximately half of them included cost effectiveness analyses for various subgroups. Interestingly, the ICER values estimated by NICE for the same subgroups showed a large variation (1X-3X fold difference) compared to ICER values estimated by manufacturers. Selected case studies highlighted that for several products NICE is recommending treatments only for subgroups whose ICER values are within the cost effectiveness threshold. **CONCLUSIONS:** New products need robust broader population and subgroup analyses for insurance coverage.

PHP18

THE EFFECT OF LAW FOR ECONOMICAL USE OF MEDICATIONS 2006 ON THE CATCHMENT POPULATION OF COMMUNITY PHARMACIES BETWEEN 2007-2010

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OBJECTIVES: In 2006 a law for the economical use of medications was introduced into the Hungarian legislation. This law – among others – facilitated the foundation of new pharmacies. The aim of our study is to analyse the effect of that legislation on the catchment population of community pharmacies. **METHODS:** Data were derived from the pharmaceutical database of the Hungarian Health Insurance Fund Administration (OEP), the only health care financing agency in Hungary. We analysed the 5 years period between 2006-2010. The main indicator of our analyses is the average population of one pharmacy (catchment population) in the counties of Hungary. **RESULTS:** The average catchment population of a pharmacy was 4933 inhabitants (($\pm$ 592, standard deviation, SD) in 2006, while in 2010 it decreased to 3.888 ($\pm$ 450) inhabitants per pharmacy. We found the largest catchment popula-